

## **REMARKS**

The Examiner has rejected Claim 15 under 35 U.S.C. § 101 because the claimed invention is not supported by either a credible asserted utility or a well-established utility. The Examiner has further rejected Claim 15 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner has also rejected claims 1-7 under 35 U.S.C. § 112, first paragraph, because the specification, while enabling for an immunogenic complex comprising gp120 bonded to a fragment of CD4, does not reasonably provide enablement for an immunogenic complex comprising gp120 bonded to a CD4 equivalent. The Examiner has further rejected claims 1-7 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Finally, the Examiner has rejected claims 1-7 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Patent No. 5,843,454, and Claim 1 of U.S. Patent No. 5,518,723. Claims 8-14 and 16-20 have been withdrawn. Claims 1-20 are currently pending. The following remarks are considered by applicant to overcome each of the Examiner's outstanding rejections to current claims 1-7 and 15. An early Notice of Allowance is therefore requested.

### **I. REJECTION OF CLAIM 15 UNDER 35 U.S.C. § 101**

On page 2 of the current Office Action, the Examiner rejects Claim 15 under 35 U.S.C. § 101 because the claimed invention is not supported by either a credible asserted utility or a well-established utility. This rejection is respectfully traversed and believed overcome in view of the following discussion.

The examiner seems to contend that Claim 15 has no credible asserted utility as it has not been established that the invention of Claim 15 can prevent the disease, or the process that can lead to the disease, that is caused by every strain of HIV. However, this misconstrues the utility of Claim 15. Specifically, the invention of Claim 14 need not prevent the disease for every strain of HIV.

A vaccine may contain more than one substance which aids in its effectiveness. For example, the flu vaccine consists of multiple substances which together inoculate people against multiple strains of influenza. One of those substances alone would not provide the same protection against influenza. “Each year the influenza virus changes and different strains become dominant.” Wikipedia, The Free Encyclopedia, [http://en.wikipedia.org/wiki/Flu\\_vaccine](http://en.wikipedia.org/wiki/Flu_vaccine) (visited on 1/26/07). “Due to the high mutability of the virus a particular vaccine formulation usually only works for about a year.” *Id.* Accordingly, the flu vaccine must be modified every year in order to provide the best protection against influenza. However, the vaccine does not make a person immune to all strains of influenza, but rather only immune to the strains that were covered in the particular flu vaccine the patient received. Each substance in the flu vaccine that helps to prevent infection of influenza has obvious utility, even though each substance alone cannot prevent all influenza strains. Moreover, the flu vaccine itself also has obvious utility, even though it does not completely prevent you from being infected by every strain of influenza.

Claim 15 states:

A vaccine comprising an immunogenically effective amount of a complex of gp120 covalently bonded to a fragment of CD4 or an equivalent thereof in a pharmaceutically acceptable medium.

Accordingly, Claim 15 does not limit itself to only the specified substances, but merely states that all the specified substances must be present. The test results contained in the current specification clearly illustrate that the composition of Claim 15 elicits a broad anti-HIV response and therefore has great utility in vaccine development and immunotherapy against HIV infection. Specification, P. 1, Lns. 26-30; P. 2, Lns. 1-2; P. 5, Lns. 23-31; P. 6, Lns. 1-11. See also Specification, Examples section, P. 12-31. Applicant’s need not prove that the invention of Claim 15 as set forth, and only as set forth, works as a vaccine against all strains of HIV. Applicants need only show that the invention of Claim 15 is has utility in the area of HIV vaccines. Throughout the specification, Applicants have more than demonstrated the usefulness and utility of the invention of Claim 15 as it relates to the field of HIV vaccines.

Therefore, Applicants respectfully assert that the Examiner's rejection of Claim 15 under 35 U.S.C. § 101, because the claimed invention is not supported by either a credible asserted utility or a well-established utility, is improper and that Claim 15 is in allowable form.

## **II. REJECTION OF CLAIM 15 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

On page 2 of the current Office Action, the Examiner rejects Claim 15 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. This rejection is respectfully traversed and believed overcome in view of the following discussion.

The Examiner asserts that the enablement requirement has not been satisfied because undue experimentation is required to make and use the full scope of the invention. In particular, that Examiner asserts that undue experimentation is required because (1) there are no working examples which suggest the desired results of a vaccine which would raise neutralizing antibodies in humans and protect against HIV infection, (2) the nature of the invention involved the complex and incompletely understood area of immune responses important in HIV Disease, and (3) the state of the prior art shows that prior vaccines designed to produce neutralizing antibody responses against HIV infection have been largely ineffective for the intended purpose. However, this line of reasoning misunderstands the intended use of Claim 15.

Claim 15 meant to be used to help develop a vaccine for HIV. The Examiner seems to be focusing on the effectiveness of Claim 15 at preventing all strains of HIV, however, this misses the point. Once again, take the example of the flu vaccine. As discussed above, the flu vaccine consists of multiple substances which together inoculate people against multiple strains of influenza. One of those substances may only be effective against a single strain, or it may take a few of those substances working in tandem to be effective against a single strain. Even though one of those substances is not effective against all influenza strains, one of ordinary skill in the art would know how to combine one substance that assists in immunization from one influenza strain with other substances that assist in immunization from other influenza strains,

such that together the various substances create a flu vaccine with effectiveness against a sufficient number of strains of influenza that people will buy it.

Here though, the question is not whether the invention of Claim 15 is effective against a sufficient number of strains of influenza such that people will buy it, but rather whether the specification has enabled one of ordinary skill in the art to practice the invention of Claim 15. The specification need not specify how to create a marketable vaccine. The specification need only provide information sufficient to inform one of ordinary skill in the art how to practice the invention for its recited utility. The specification has set forth that the invention of Claim 15 is useful in the development of HIV vaccines. The specification has also set forth how to use the invention of Claim 15 to assist in the creation of a vaccine. This is all the enablement that is required.

Therefore, Applicants respectfully assert that the Examiner's rejection of Claim 15 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement, is improper and that Claim 15 is in allowable form.

### **III. REJECTION OF CLAIMS 1-7 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH – SCOPE OF ENABLEMENT**

On page 7 of the current Office Action, the Examiner rejects claims 1-7 under 35 U.S.C. § 112, first paragraph, because the specification, while enabling for an immunogenic complex comprising gp120 bonded to a fragment of CD4, does not reasonably provide enablement for an immunogenic complex comprising gp120 bonded to a CD4 equivalent. This rejection is respectfully traversed and believed overcome in view of the following discussion.

Claim 1 states:

An immunogenic complex comprising gp120 covalently bonded to a fragment of CD4 or an equivalent thereof.

The phrase “CD4 equivalent molecules” is described in the specification as including any molecule that mimics CD4 in conformation and/or induces a conformational change on HIV-1 gp120 that is similar to that induced by CD4. Examiner argues that, as a result of this description, neither the instant claims nor the specification provides specific structure description about an equivalent of CD4. However, this claim analysis disregards the legal concept called the doctrine of equivalents.

The doctrine of equivalents allows a patent owner to hold as an infringement a product or process that does not correspond to the literal terms of a patent's claim but performs substantially the same function in substantially the same way to obtain the same result as the claimed subject matter. This theory of infringement liability is available whether or not the claim specifically references equivalents, nor is a specific description of equivalents required to be present in the claim in order to find infringement by the doctrine of equivalents.

The purpose of stating “or an equivalent thereof” in Claim 1 is merely to make it abundantly clear that Claim 1 also includes equivalents, as is inherently included under the theory of doctrine of equivalents. Accordingly, it is not required that the Applicants provide the specific structure description of equivalents of CD4. Such a determination will be made, if ever, at trial when determining, as specified by the doctrine of equivalents, whether the accused infringing product or process performs substantially the same function in substantially the same way to obtain the same result as the claimed subject matter.

Therefore, Applicants respectfully assert that Examiner’s rejection of claims 1-7 under 35 U.S.C. § 112, first paragraph, because the specification, while enabling for an immunogenic complex comprising gp120 bonded to a fragment of CD4, does not reasonably provide enablement for an immunogenic complex comprising gp120 bonded to a CD4 equivalent, is improper and that claims 1-7 are in allowable form.

**IV. REJECTION OF CLAIMS 1-7 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH – WRITTEN DESCRIPTION**

On page 9 of the current Office Action, the Examiner rejects claims 1- under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed and believed overcome in view of the following discussion.

Examiner's arguments for this rejection seem to miss the relevance of the phrase in Claim 1 of "or an equivalent thereof". As stated above, the purpose of stating "or an equivalent thereof" in Claim 1 is merely to make it abundantly clear that Claim 1 also includes equivalents, as is inherently included under the theory of doctrine of equivalents. Accordingly, it is not required that the scope of "an equivalent thereof" be specifically limited. Such a determination of the scope of equivalents will be made, if ever, at trial when determining, as specified by the doctrine of equivalents, whether the accused infringing product or process performs substantially the same function in substantially the same way to obtain the same result as the claimed subject matter.

Therefore, Applicants respectfully assert that Examiner's rejection of claims 1-7 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, is improper and that claims 1-7 are in allowable form.

**V. REJECTION OF CLAIMS 1-7 ON THE GROUND OF NONSTATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING**

On page 10 of the current Office Action, the Examiner rejects claims 1-7 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Patent No. 5,843,454, and Claim 1 of U.S. Patent No. 5,518,723. This rejection is respectfully traversed and believed overcome in view of the following discussion.

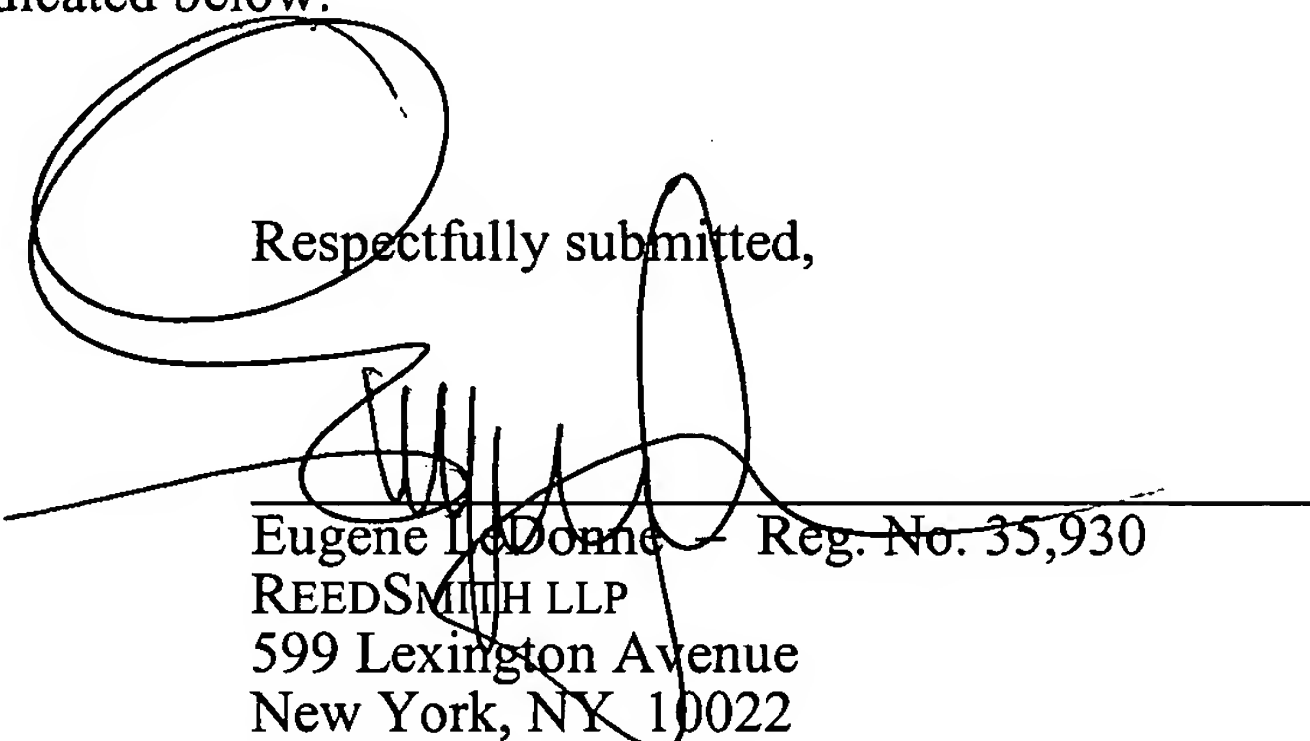
Applicants respectful assert that the above rejections can be eliminated by the filing of a terminal disclaimer and that such a disclaimer need not be filed until the the claims are



otherwise determined to be allowable by the Examiner. Accordingly, Applicants respectfully reserve the right to file a terminal disclaimer and assert that the 1-7 are otherwise in allowable form.

Based upon the above remarks, Applicant respectfully requests reconsideration of this application and its early allowance. Should the Examiner feel that a telephone conference with Applicant's attorney would expedite the prosecution of this application, the Examiner is urged to contact him at the number indicated below.

Respectfully submitted,



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